

**MALIGNANT ODONTOGENIC
TUMOURS**

**STRUCTURED REPORTING
PROTOCOL**

(1st Edition 2019)

Incorporating the:

International Collaboration on Cancer Reporting (ICCR)

Malignant Odontogenic Tumours Dataset

www.ICCR-Cancer.org

Core Document versions:

- ICCR dataset: Malignant Odontogenic Tumours Dataset 1st edition
- World Health Organization (WHO). Classification of Head and Neck Tumours. 4th edition.

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Scope

This protocol contains standards and guidelines for the structured reporting of malignant odontogenic tumours. The protocol has been developed for the reporting of biopsy and resection specimens for malignant primary odontogenic tumours. Malignant neoplasms arising in the nasal cavity and paranasal sinuses, oral cavity, [salivary glands](#), trachea, pharynx and larynx are dealt with in [separate protocols](#). Bone, soft tissue and lymphoma protocols will be separately listed. In addition, [neck dissections and nodal excisions](#) are dealt with in a separate protocol, and this protocol should be used in conjunction, where applicable.

Dataset items should be completed, taking into account all relevant information, including clinical, pathological and radiological.

Structured reporting aims to improve the completeness and usability of pathology reports for clinicians, and improve decision support for cancer treatment. This protocol can be used to define and report the minimum data set but the structure is scalable and can equally accommodate a maximum data set or fully comprehensive report.

Abbreviations

AJCC	American Joint Committee on Cancer
CG	Commentary for a guideline
CS	Commentary for a standard
ICCR	International Collaboration on Cancer Reporting
LIS	Laboratory information system
LVI	Lymphovascular invasion
RCPA	Royal College of Pathologists of Australasia
TNM	Tumour-node-metastasis
UICC	International Union Against Cancer
WHO	World Health Organization

Definitions

The table below provides definitions for general or technical terms used in this protocol. Readers should take particular note of the definitions for 'standard', 'guideline' and 'commentary', because these form the basis of the protocol.

Ancillary study	An ancillary study is any pathology investigation that may form part of a cancer pathology report but is not part of routine histological assessment.
Clinical information	Patient information required to inform pathological assessment, usually provided with the specimen request form, also referred to as "pre-test information".
Commentary	<p>Commentary is text, diagrams or photographs that clarify the standards (see below) and guidelines (see below), provide examples and help with interpretation, where necessary (not every standard or guideline has commentary).</p> <p>Commentary is used to:</p> <ul style="list-style-type: none">• define the way an item should be reported, to foster reproducibility• explain why an item is included (e.g., how does the item assist with clinical management or prognosis of the specific cancer).• cite published evidence in support of the standard or guideline• state any exceptions to a standard or guideline. <p>In this document, commentary is prefixed with 'CS' (for commentary on a standard) or 'CG' (for commentary on a guideline), numbered to be consistent with the relevant standard or guideline, and with sequential alphabetic lettering within each set of commentaries (e.g., CS1.01a, CG2.05b).</p>
General commentary	<p>General commentary is text that is not associated with a specific standard or guideline. It is used:</p> <ul style="list-style-type: none">• to provide a brief introduction to a chapter, if necessary• for items that are not standards or guidelines but are included in the protocol as items of potential importance, for which there is currently insufficient evidence to recommend their inclusion. (Note: in future reviews of protocols, such items may be reclassified as either standards or guidelines, in line with diagnostic and prognostic advances, following evidentiary review).

Guideline	<p>Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are unanimously agreed should be included in the dataset but are not supported by National Health and Medical Research Council (NHMRC) level III-2 evidence.¹ These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management.</p> <p>Guidelines include key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion e.g., macroscopic tumour details, block identification key, may be included as either required or recommended elements by consensus of the expert committee. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail.</p> <p>Guidelines are not used for research items.</p> <p>In this document, guidelines are prefixed with 'G' and numbered consecutively within each chapter (e.g., G1.10).</p>
Macroscopic findings	Measurements, or assessment of a biopsy specimen, made by the unaided eye.
Microscopic findings	In this document, the term 'microscopic findings' refers to histomorphological assessment.
Predictive factor	A predictive factor is a measurement that is associated with response or lack of response to a particular therapy.
Prognostic factor	A prognostic factor is a measurement that is associated with clinical outcome in the absence of therapy or with the application of a standard therapy. It can be thought of as a measure of the natural history of the disease.
Standard	<p>Standards are mandatory, as indicated by the use of the term 'must'. Standards are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the NHMRC levels of evidence¹ document). In rare circumstances, where level III-2 evidence is not available an element may be made a Standard where there is unanimous agreement in the expert committee. An appropriate staging system e.g., Pathological TNM staging would normally be included as a required element. These elements must be recorded and at the discretion of the pathologist included in the pathology report according to the needs of the recipient of the report.</p> <p>The summation of all standards represents the minimum dataset for the cancer.</p> <p>In this document, standards are prefixed with 'S' and numbered consecutively within each chapter (e.g., S1.02).</p>

Structured report	A report format which utilises standard headings, definitions and nomenclature with required information.
Synoptic report	A structured report in condensed form (as a synopsis or precis).
Synthesis	<p>Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new.</p> <p>The Oxford dictionary defines synthesis as “the combination of components or elements to form a connected whole”.</p> <p>In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.</p>

Introduction

Malignant Odontogenic Tumours

This protocol is based almost exclusively on professional judgement because there is no high level evidence to support individual data items.² Pathologists with limited specialist expertise in reporting odontogenic lesions are strongly encouraged to seek second opinions where appropriate. To reduce the risk for clinical misunderstanding, it is recommended that pathologists consistently utilise a combination of astute reporting and discussion at multidisciplinary meetings, highlighting diagnostic features of unproven clinical significance.

Malignant odontogenic tumours are rare, and published series are often not homogeneous by tumour type, stage or treatment, making conclusions about the value of individual items impossible. In general, those tumours that show aggressive histological features are more likely to be associated with poor survival, but this tumour group is characterised by unpredictability of behaviour; low grade tumours may recur or metastasize many years after excision. For all types, local recurrence and metastasis are poor prognostic features^{3,4} and outcomes are relatively poor after local recurrence.⁵⁻⁷

Published mortality rates are limited by short follow up. Ameloblastic carcinoma appears to carry a better prognosis than other types, for reasons that are unclear,⁸ though maxillary lesions behave worse than mandibular,⁹ with up to one third of maxillary lesions resulting in pulmonary metastases. Sclerosing odontogenic carcinoma is unusual. Despite extensive perineural spread, this carcinoma carries a relatively good prognosis.^{10,11}

Odontogenic sarcomas are overall of low grade and tend to show local recurrence rather than distant spread and thus carry a better prognosis than other types of sarcoma, but still have significant mortality and recurrence rates.^{12,13}

There are no validated grading systems for odontogenic tumours. For primary intraosseous squamous carcinoma, the conventional squamous carcinoma grade has some value.¹⁴

Margin status after surgical excision is thought to be the key prognostic feature^{3,15-18} and the best evidence relates to ameloblastic carcinoma,⁸ primary intraosseous carcinoma,^{5,14} and clear cell carcinoma.¹⁵ Tumour dimensions and localisation are important prognostic features. Carcinomas arising in or limited to cysts therefore carry a better prognosis than those with widespread infiltration.¹⁹

As with most head and neck surgical resections, clearances may be very small or inadequate and extension into soft tissues beyond the periosteum is usually associated with a significant risk of local recurrence. The prognosis is worse when incomplete excision is in the infratemporal fossa or base of skull areas and therefore the anatomical site of involved margins should be specified clearly.

The role for adjuvant or salvage radiotherapy remains to be defined. The literature does not provide useful information on radiotherapy indications or the intent when it has been used. Despite use to control incompletely excised malignant odontogenic tumours, its

value often appears limited^{15,16} but has support in large series⁸ and is usually considered most effective as planned multimodality treatment.

No staging elements are included because there is no staging system for malignant odontogenic tumours recommended by the Union for International Cancer Control (UICC) or American Joint Committee on Cancer (AJCC), although staging based on size criteria has been suggested.²⁰

Benefits of structured reporting

The pathology report lays the foundation for a patient's cancer journey and conveys information which:

- Provides the definitive diagnosis
- Includes critical information for Tumour-Node-Metastasis (TNM) staging
- Evaluates the adequacy of the surgical excision
- Provides morphological and biological prognostic markers which determine personalised cancer therapy

However, the rapid growth in ancillary testing such as immunohistochemistry, flow cytometry, cytogenetics, and molecular studies, have made the task of keeping abreast of advances on specific cancer investigations extremely difficult for pathologists. The use of structured reporting checklists by pathologists ensures that all key elements are included in the report specifically those which have clinical management, staging or prognostic implications. Consequently minimum or comprehensive datasets for the reporting of cancer have been developed^{21,22} around the world. Both the United Kingdom,²³ and United States²⁴ have produced standardised cancer reporting protocols or "datasets" for national use for many years.

The use of cancer reporting checklists improves completeness and quality of cancer reporting and thereby ensures an improved outcome for cancer patients. This has long term cost implications for public health by ensuring the most effective and timely treatment based on accurate and complete information.

The use of a structured reporting format also facilitates easy extraction of the necessary information by secondary users of the information i.e., cancer registries.

Importance of histopathological reporting

The information contained within a pathology report includes prognostic information for the patient and treating clinical team. The content will assist in subsequent management, whether this may be surveillance, further surgery, radiotherapy or chemotherapy, or a combination of these modalities.

International Collaboration on Cancer Reporting

The International Collaboration on Cancer Reporting (ICCR), founded in 2011 by the Australasian (RCPA), United States College of American Pathologists (US CAP) and Royal College of Pathologists United Kingdom (RCPATH UK) Colleges of Pathology and the Canadian Association of Pathology - Association Canadienne des Pathologistes (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), was established to explore the possibilities of a collaborative approach to the development of common,

internationally standardised and evidence-based cancer reporting protocols for surgical pathology specimens.

The ICCR, recognising that standardised cancer datasets have been shown to provide significant benefits for patients and efficiencies for organisations through the ease and completeness of data capture²⁵⁻²⁸ undertook to use the best international approaches and the knowledge and experience of expert pathologists, and produce cancer datasets which would ensure that cancer reports across the world will be of the same high quality – ensuring completeness, consistency, clarity, conciseness and above all, clinical utility.

Representatives from the four countries participating in the initial collaboration undertook a pilot project in 2011 to develop four cancer datasets - Lung, Melanoma, Prostate (Radical Prostatectomy), and Endometrium. Following on from the success of this pilot project, the ICCR was joined by the European Society of Pathology (ESP) in 2013 and in 2014 incorporated a not-for-profit organisation focussed on the development of internationally agreed evidence-based datasets developed by world leading experts. The ICCR datasets are made freely available from its website www.ICCR-Cancer.org

Design of this protocol

This structured reporting protocol has been developed using the ICCR dataset on malignant odontogenic tumours as the foundation.

This protocol includes all of the ICCR cancer dataset elements as well as additional information, elements and commentary as agreed by the RCPA expert committee. It provides a comprehensive framework for the assessment and documentation of pathological features of malignant odontogenic tumours.

ICCR dataset elements for malignant odontogenic tumours are included verbatim. ICCR Core elements are mandatory and therefore represented as standards in this document. ICCR Non-core elements, that is, those which are not mandatory but are recommended, may be included as guidelines or upgraded to a standard based on the consensus opinion of the local expert committee.

The ICCR elements are identified in each chapter with the ICCR logo placed before the Standard or Guideline number or bullet and the ICCR element description and commentary is boarded by a grey box as shown below:

 S3.01	The histological tumour type must be recorded.
--	---

Additional commentary by the RCPA expert committee may be added to an ICCR element but is not included in the grey bordered area nor indicated with an ICCR logo e.g.,

 G2.03	If present, the laterality of the lymph nodes submitted may be recorded as left, right or bilateral.
---	--

CS2.03a If present, record site and number. All lymph node tissue

should be submitted for histological examination.

Further information on the ICCR is available at www.iccr-cancer.org

Checklist

Consistency and speed of reporting is improved by the use of discrete data elements recorded from the checklist. Items suited to tick boxes are distinguished from more complex elements requiring free text or narrative. A structured or discrete approach to responses is favoured, however the pathologist is encouraged to include free text or narrative where necessary to document any other relevant issues, to give reasons for coming to a particular opinion and to explain any points of uncertainty.

Report format

The structure provided by the following chapters, headings and subheadings describes the elements of information and their groupings, but does not necessarily represent the format of either a pathology report (Chapter 7) or checklist (Chapter 6). These, and the structured pathology request form (Appendix 1) are templates that represent information from this protocol, organised and formatted differently to suit different purposes.

Key documentation

- *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols, Royal College of Pathologists of Australasia, 2009.*²⁹
- *World Health Organization (WHO). Classification of Head and Neck Tumours., 4th Edition. El-Naggar AK, Chan JKC, Grandis JR, Takata T, Slotweg PJ (editors). Lyon, France: IARC Press;2017.*³⁰

Changes since last edition

Not applicable.

Authority and development

This section provides information about the process undertaken to develop this protocol.

This 1st edition of the protocol is an amalgam of two separate processes:

1. This protocol is based on the ICCR dataset – Malignant Odontogenic Tumours 1st edition. All ICCR elements from this dataset, both core (mandatory) and non-core (optional), are included in this protocol, verbatim. (It should be noted that RCPA feedback from all Anatomical Pathology fellows and specifically the local expert committee was sought during the development process of the ICCR dataset.) Details of the ICCR development process and the international expert authoring committee responsible for the ICCR dataset are available on the ICCR website: iccr-cancer.org.
2. Additional elements, values and commentary have been included as deemed necessary by the local expert committee. In addition, the standard inclusions of RCPA protocols e.g., example reports, request information etc, have also been added.

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Stakeholders

ACT Cancer Registry

ACT Health

Australian and New Zealand Association of Oral & Maxillofacial Surgeons

Australian and New Zealand Head and Neck Cancer Society

Australian Cancer Network

Australian Commission on Safety and Quality in Health Care

Australian Digital Health Agency

Australian Institute of Health and Welfare

Australian Society of Otolaryngology Head and Neck Surgery

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Cancer Australia

Cancer Council ACT

Cancer Council Queensland

Cancer Council Victoria

Cancer Council Western Australia

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Cancer Voices NSW

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Department of Health, Australia

Health Informatics Society of Australia (HISA)

Independent Review Group of Pathologists

International Academy of Pathology (IAP)

Medical Oncology Group of Australia

Medical Software Industry Association (MSIA)

Ministry of Health, New Zealand

National Pathology Accreditation Advisory Council (NPAAC)

New Zealand Cancer Registry

Northern Territory Cancer Registry

Pathology Australia

Public Pathology Australia

Queensland Cooperative Oncology Group (QCOG)

RCPA Anatomical Pathology Advisory Committee (APAC)

Representatives from laboratories specialising in anatomical pathology across Australia

Royal Australasian College of Physicians (RACP)

Royal Australasian College of Surgeons (RACS)

Royal Australian and New Zealand College of Radiologists (RANZCR)
Royal Australian College of General Practitioners (RACGP)
Royal College of Pathologists of Australasia (RCPA)
South Australia Cancer Registry
Standards Australia
Tasmanian Cancer Registry
Victorian Cancer Registry
Western Australia Clinical Oncology Group (WACOG)
Western Australian Cancer Registry

Development process

This protocol has been developed following the ten-step process set out in *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols*.²⁹

Where no reference is provided, the authority is the consensus of the local expert group for local inclusions and the ICCR Dataset Authoring Committee for ICCR components denoted with the ICCR logo.

1 Pre-analytical

This chapter relates to information that should be recorded on receipt of the specimen in the laboratory.

The pathologist is reliant on the quality of information received from the clinicians or requestor. Some of this information may be received in generic pathology request forms, however, the additional information required by the pathologist specifically for the reporting of malignant odontogenic tumours, is outlined in Appendix 1. Appendix 1 also includes a standardised request information sheet that may be useful in obtaining all relevant information from the requestor.

Surgical handling procedures affect the quality of the specimen and recommendations for appropriate surgical handling are included in Appendix 1.

S1.01 All demographic information provided on the request form and with the specimen must be recorded.

- CS1.01a The Royal College of Pathologists of Australasia (RCPA) *The Pathology Request-Test-Report Cycle – Guidelines for Requesters and Pathology Providers* must be adhered to.³¹ This document specifies the minimum information to be provided by the requesting clinician for any pathology test.
- CS1.01b Document whether or not the patient identifies as Aboriginal and/or Torres Strait Islander in Australia or Māori in New Zealand. This is in support of government initiatives to monitor the health of those who identify as indigenous, particularly in relation to cancer.
- CS1.01c The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).

S1.02 All clinical information as documented on the request form must be recorded verbatim.

- CS1.02a The request information may be recorded as a single text (narrative) field or it may be recorded in a structured format.
- CS1.02b In most cases, all clinical information should be transcribed: however, in a small number of cases the pathologist may exercise discretion regarding the inclusion of provided clinical information, for instance, possibly erroneous information or information that may impact on patient privacy. In such case reference should be made as to the location of the complete clinical information e.g., "Further clinical information is available from the scanned request form."

G1.01 The copy doctors requested on the request form should be recorded.

S1.03 The pathology accession number of the specimen must be recorded.

S1.04 The principal clinician involved in the patient's care and responsible for investigating the patient must be recorded.

CS1.04a The principal clinician should provide key information regarding the clinical presentation of the patient. Follow up may be required with the principal clinician for a number of reasons:

- The clinical assessment and staging may be incomplete at the time of biopsy.
- The pathology request is often authored by the clinician performing the surgical excision/biopsy rather than the clinician who is investigating and managing the patient.
- The identity of this clinician is often not indicated on the pathology request form

In practice therefore, it is important in such cases that the reporting pathologist should be able to communicate with the managing clinician for clarification.

CS1.04b The Australian Healthcare identifiers i.e., Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be included, where possible, to identify the principal clinician involved in the patient's care.

G1.02 Any clinical information received in other communications from the requestor or other clinician should be recorded together with the source of that information.

2 Specimen handling and macroscopic findings

This chapter relates to the procedures required after the information has been handed over from the requesting clinician, and the specimen has been received in the laboratory.

Specimen handling

- Detailed fixation and specimen handling instructions are available from the RCPA online Cut-up Manual:
<https://www.rcpa.edu.au/Manuals/Macroscopic-Cut-Up-Manual>
- **The specimen must be handled in a systematic and thorough fashion to ensure completeness and accuracy of pathological data.**

Macroscopic findings

S2.01 The labelling of the specimen(s) must be clearly recorded.

	S2.02	The specimen(s) submitted must be recorded.
	S2.03	The macroscopic tumour site(s) must be recorded.
	S2.04	The maximum dimension of largest tumour must be recorded.
	CS2.04a	Due to the nature of odontogenic lesions, reference to any imaging or consultation with a radiologist is recommended and maximum tumour dimension may be determined by a combination of methods including macroscopy, specimen or clinical radiology and microscopy. Size criteria for possible staging have been suggested, ²⁰ with smaller tumour size associated with a better overall survival. ⁸
	G2.01	Additional dimensions of the largest tumour may be recorded.

S2.05 A differential ink application and block identification key listing the nature and origin of all tissue blocks must be recorded.

- CS2.05a The colours of the ink used to designate the various surfaces (particularly superficial and deep) should be clearly stated in the macroscopic description to guide margin assessment.
- CS2.05b The origin/designation of all tissue blocks should be recorded. This information should be documented in the final pathology report and is particularly important should the need for internal or external review arise.

The reviewer needs to be clear about the origin of each block in order to provide an informed specialist opinion. If this information is not included in the final pathology report, it should be available on the laboratory computer system and relayed to the reviewing pathologist. Utilising photography to record the specimen can be of benefit and should be considered.

Recording the origin/designation of tissue blocks also facilitates retrieval of blocks for further immunohistochemical or molecular analysis, research studies or clinical trials.

- G2.02 A descriptive or narrative field should be provided to record any macroscopic information that is not recorded in the above standards and guidelines, and that would normally form part of the macroscopic description.
 - CG2.02a The traditional macroscopic narrative recorded at the time of specimen dissection is often reported separately from the cancer dataset. Although this remains an option, it is recommended that macroscopic information be recorded within the overall structure of this protocol.
 - CG2.02b Much of the information recorded in a traditional macroscopic narrative is covered in the standards and guidelines above and in many cases, no further description is required.
 - CG2.02c A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.
 - CG2.02d Where the LIS offers an electronic interface for structured data entry the need for narrative can be significantly reduced to describe only information not otherwise captured.

3 Microscopic findings

This section relates to purely histological or morphological assessment. Information derived from multiple investigational modalities, or from two or more chapters, is described in Chapter 5.

 S3.01	The histological tumour type must be recorded.	
	CS3.01a	Refer to Appendix 4.
	CS3.01b	All odontogenic and maxillofacial bone tumours should be given a type based on the most recent edition of the World Health Organization (WHO) Classification of Head and Neck Tumours. ³²
 S3.02	For primary intraosseous cell carcinoma, the histological tumour grade must be recorded.	
	CS3.02a	For primary intraosseous squamous carcinoma, the conventional squamous carcinoma grade is used.
 S3.03	The presence or absence of necrosis must be recorded.	
	CS3.03a	Necrosis is not only a tool to aid in grading of tumours, but in many instances, the presence of necrosis helps to confirm a diagnosis of malignancy in odontogenic tumours in general. Thus, while large clinical series of these rare tumours are not available, there is strong support that reporting necrosis aids in diagnosis, grade and tumour classification. ^{3,33}
 G3.01	The extent of invasion should be recorded.	
	CG3.01a	Use Figure 1 to define the sites involved. Extent of invasion is best assessed by a combination of macroscopic, microscopic and radiographic information.
 S3.04	The presence or absence of lymphovascular invasion must be recorded.	
 S3.05	The presence or absence of perineural invasion must be recorded.	
 S3.06	The surgical margin status must be reported.	
	CS3.06a	<p>Margin status is thought to be a key prognostic item. Surgical clearance is often by only a small margin and it is important to know whether the excision is marginal around a large part of the periphery of the tumour or just focally, as reoperation may be possible.</p> <p>The prognosis is worse where an incomplete excision is located in the infratemporal fossa or base of skull areas and therefore the anatomical site of involved margins</p>

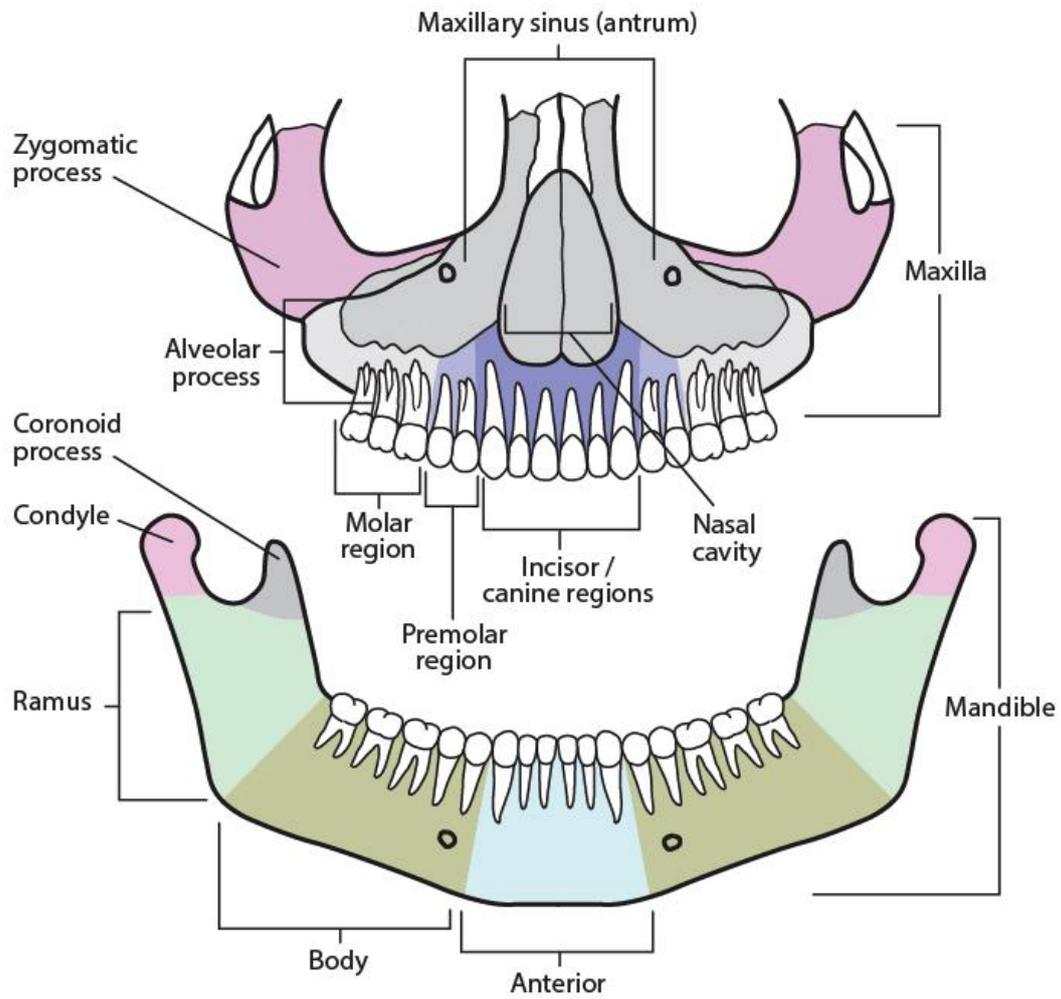
		should be specified clearly.
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G3.02 Radiation induced tissue damage can be recorded.

G3.02a An observation regarding radiation induced tissue damage can be provided if the request form includes history regarding neoadjuvant radiotherapy or recurrence in a previous radiotherapy field. Currently, there are no internationally standardised guidelines for evaluation of radiotherapy induced damage or whether this should influence any decisions regarding further radiotherapy. However, description of the radiotherapy induced tissue damage will allow collection of this data to develop evidence base for the future. Features such as stromal atypia, hyalinization, interstitial fibrosis, small vessel endothelial proliferation, and other features may be mentioned.

G3.03 Any additional relevant microscopic comments should be recorded.

Figure 1. Diagram showing anatomical sites for extent of involvement.
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4 Ancillary studies findings

Ancillary studies may be used to determine lineage, clonality or disease classification or subclassification; as prognostic biomarkers; or to indicate the likelihood of patient response to specific biologic therapies.

 G4.01	Whether or not ancillary tests are performed should be recorded and the results incorporated into the pathology report.	
	CG4.01a	There are a number of immunohistochemical and molecular studies that may be relevant. Some already have potential but unproven therapeutic benefit. Examples include; <i>Ewing sarcoma breakpoint region 1 (EWSR1)</i> rearrangements in clear cell odontogenic carcinoma ³⁴ and <i>BRAF</i> v600E mutation in ameloblastic carcinoma. ³⁵ Such tests may also increase diagnostic certainty and, if performed, should be recorded.

CG4.01b Consider utilising appropriate fixation and decalcification methods (e.g., Osteosoft or other EDTA-based solutions) for bony specimens, in order to preserve some material for molecular studies.

5 Synthesis and overview

Information that is synthesised from multiple modalities and therefore cannot reside solely in any one of the preceding chapters is described here.

For example, *tumour stage* is synthesised from multiple classes of information – clinical, macroscopic and microscopic.

By definition, synthetic elements are inferential rather than observational, often representing high-level information that is likely to form part of the 'Summary' or 'Diagnosis' section in the final formatted report.

Overarching case comment is synthesis in narrative format. Although it may not necessarily be required in any given report, the provision of the facility for overarching commentary in a cancer report is essential.

G5.01 The 'Diagnostic summary' section of the final formatted report should include:

- a. Type of specimen
- b. Tumour site
- c. Maximum tumour dimension
- d. Tumour type
- e. Histological grade
- f. Necrosis
- g. Perineural invasion
- h. Lymphovascular invasion
- i. Involved or close margins with measurements (specify involvement of bony and/or soft tissue margins)

S5.01 The reporting system must provide a field for free text or narrative in which the reporting pathologist can give overarching case comment if required.

CS5.01a This field may be used, for example, to:

- explain the decision-making pathway, or any elements of clinicopathological ambiguity, or factors affecting diagnostic certainty, thereby allowing communication of diagnostic subtlety or nuance that is beyond synoptic capture
- give recommendations for further action or investigation
- document further consultation or results still pending

- CS5.01b Use of this field is at the discretion of the reporting pathologist.
- G5.02 The edition/version number of the RCPA protocol on which the report is based should be included on the final report.
 - CG5.02a For example, the pathology report may include the following wording at the end of the report: "the data fields within this formatted report are aligned with the criteria as set out in the RCPA document "XXXXXXXXXX" XXXX Edition dated XXXXXXXX".

6 Structured checklist

The following checklist includes the standards and guidelines for this protocol which must be considered when reporting, in the simplest possible form. The summation of all 'standards' is equivalent to the 'minimum data set' for this cancer. For emphasis, standards (mandatory elements) are formatted in bold font.

S6.01 The structured checklist provided may be modified as required but with the following restrictions:

- a. All standards and their respective naming conventions, definitions and value lists must be adhered to.**
- b. Guidelines are not mandatory but are recommendations and where used, must follow the naming conventions, definitions and value lists given in the protocol.**

G6.01 The order of information and design of the checklist may be varied according to the laboratory information system (LIS) capabilities and as described in *Functional Requirements for Structured Pathology Reporting of Cancer Protocols*.³⁶

CG6.01a Where the LIS allows dissociation between data entry and report format, the structured checklist is usually best formatted to follow pathologist workflow. In this situation, the elements of synthesis or conclusions are necessarily at the end. The report format is then optimised independently by the LIS.

CG6.01b Where the LIS does not allow dissociation between data entry and report format, (for example where only a single text field is provided for the report), pathologists may elect to create a checklist in the format of the final report. In this situation, communication with the clinician takes precedence and the checklist design is according to principles given in Chapter 7.

G6.02 Where the checklist is used as a report template (see G6.01), the principles in Chapter 7 and Appendix 2 apply.

CG6.02a All extraneous information, tick boxes and unused values should be deleted.

G6.03 Additional comment may be added to an individual response where necessary to describe any uncertainty or nuance in the selection of a prescribed response in the checklist. Additional comment is not required where the prescribed response is adequate.

Item descriptions in italics are conditional on previous responses.

Values in all caps are headings with sub values.

S/G	Item description	Response type	Conditional
Pre-analytical			
S1.01	Demographic information provided		
S1.02	Clinical information provided on request form	Not provided OR Text OR Structured entry as below:	
	CLINICAL INFORMATION		
	Anatomical site	Text	
	Laterality of the lesion	Single selection value list: <ul style="list-style-type: none"> • Not stated • Left • Right 	
	Clinical history	Text OR Not stated	
	Clinical diagnosis or	Text	

	differential diagnosis		
	Type of operation	<p>Not specified</p> <p>OR</p> <p>Multi select value list (select all that apply):</p> <ul style="list-style-type: none"> • Debulking/curettage • Biopsy (excisional, incisional), <i>specify</i> • Resection, <i>specify</i> • Neck (lymph node) dissection*, <i>specify</i> • Other, <i>specify</i> <p><u>Notes:</u></p> <p><i>If a neck dissection is submitted, then a separate protocol is used to record the information.</i></p>	
	Neoadjuvant therapy	<p>Single selection value list:</p> <ul style="list-style-type: none"> • Information not provided • Not administered • Administered, <i>specify type (select all that apply):</i> <ul style="list-style-type: none"> ○ Chemotherapy ○ Radiotherapy ○ Targeted therapy, <i>specify if available</i> 	

		<ul style="list-style-type: none"> ○ Immunotherapy, <i>specify if available</i> ○ Time interval since therapy, <i>specify</i> 	
	New primary lesion or recurrence (if previous focal therapy)	Single selection value list: <ul style="list-style-type: none"> • New primary • Recurrence – regional, <i>describe</i> • Recurrence – distant, <i>describe</i> 	
G1.01	Copy doctors recorded	Text	
S1.03	Pathology accession number	Alpha-numeric	
S1.04	Principal clinician	Text	
G1.02	Comments	Text	
Macroscopic findings			
S2.01	Specimen labelled as	Text	
 S2.02	Specimen submitted	Not specified OR Multi selection value list (select all that apply): <ul style="list-style-type: none"> • Biopsy (excisional, incisional), <i>specify</i> • Debulking/curettage • Surgical resection, <i>specify</i> • Neck (lymph node) dissection*, 	

		<p><i>specify</i></p> <ul style="list-style-type: none"> • Other, <i>specify</i> <p><u>Notes:</u></p> <p><i>If a neck dissection is submitted, then a separate protocol is used to record the information.</i></p>	
	<p>S2.03 Tumour site</p>	<p>Cannot be assessed</p> <p>OR</p> <p>Multi selection value list (select all that apply):</p> <p><u>Laterality</u></p> <ul style="list-style-type: none"> ○ Left ○ Midline ○ Right ○ Laterality not specified <ul style="list-style-type: none"> • Mandible <ul style="list-style-type: none"> ○ Ramus ○ Condyle ○ Coronoid process ○ Body ○ Anterior • Maxilla <ul style="list-style-type: none"> ○ Nasal cavity/paranasal sinus (maxillary sinus) 	

		<ul style="list-style-type: none"> ○ Molar region alveolar process ○ Premolar region alveolar process ○ Incisor/canine region alveolar process ○ Zygomatic process • Extraosseous, <i>specify site</i> • Other, <i>specify including laterality</i> 	
	S2.04	Maximum tumour dimension	Cannot be assessed, <i>specify</i> OR Numeric: __mm
	G2.01	Additional dimensions (largest tumour)	Numeric: __x__mm
	S2.05	Differential ink application and block identification key	Text
	G2.02	Additional macroscopic comments	Text
Microscopic findings			
	S3.01	Histological tumour type	Cannot be assessed, <i>specify</i> OR Multi selection value list (select all that apply):

		<ul style="list-style-type: none"> • Odontogenic carcinomas <ul style="list-style-type: none"> ○ Ameloblastic carcinoma ○ Primary intraosseous carcinoma, not otherwise specified (NOS) ○ Sclerosing odontogenic carcinoma ○ Clear cell odontogenic carcinoma ○ Ghost cell odontogenic carcinoma • Odontogenic carcinosarcoma • Odontogenic sarcomas • Other (hybrid etc.), <i>specify</i> 	
	S3.02 Histological grade <i>(For primary intraosseous cell carcinoma only)</i>	Single selection value list: <ul style="list-style-type: none"> • Not applicable • GX: Cannot be assessed, <i>specify</i> • G1: Well differentiated • G2: Moderately differentiated • G3: Poorly differentiated 	
	S3.03 Necrosis	Single selection value list: <ul style="list-style-type: none"> • Cannot be assessed, <i>specify</i> • Not identified • Present 	

	G3.01 Extent of invasion	Single selection value list: <ul style="list-style-type: none"> • Not identified • Entirely intraosseous • Cortex perforated but extent limited by periosteum • Infiltration into soft tissue beyond the periosteum • Other, <i>specify</i> 	
	S3.04 Lymphovascular invasion	Single selection value list: <ul style="list-style-type: none"> • Cannot be assessed, <i>specify</i> • Not identified • Present 	
	S3.05 Perineural invasion	Single selection value list: <ul style="list-style-type: none"> • Cannot be assessed, <i>specify</i> • Not identified • Present 	

 S3.06	Margin status	Single selection value list: <ul style="list-style-type: none"> • Cannot be assessed, specify • Not involved • Involved <ul style="list-style-type: none"> ○ Bony margin ○ Soft tissue margin ○ Other, <i>specify</i> 	<i>If not involved by invasive carcinoma, record the distance from closest margin and specify site of closest margin, if possible</i> <i>If involved specify margin(s)/anatomical site if possible</i>
G3.02	Radiation induced tissue damage	Single selection value list: <ul style="list-style-type: none"> • Not identified • Identified, <i>specify</i> • Cannot be assessed, <i>specify</i> 	<i>If identified specify a description of induced damage, if possible.</i> <i>If cannot be assessed, specify a reason, if possible.</i>
G3.03	Additional microscopic comment	Text	
Ancillary findings			
 G4.01	Ancillary studies	Single selection value list: <ul style="list-style-type: none"> • Not performed • Performed, <i>specify</i> 	
Synthesis and overview			
G5.01	Diagnostic summary Include: <ol style="list-style-type: none"> a. Type of specimen b. Tumour site 	Text	*Specify involvement of bony and/or soft tissue margins.

	<ul style="list-style-type: none"> c. Maximum tumour dimension d. Tumour type e. Histological grade f. Necrosis g. Lymphovascular invasion h. Perineural invasion i. Involved or close margins with measurements* 		
S5.01	Overarching comment	Text	
G5.02	Edition/version number of the RCPA protocol on which the report is based.	Text	

7 Formatting of pathology reports

Good formatting of the pathology report is essential for optimising communication with the clinician, and will be an important contributor to the success of cancer reporting protocols. The report should be formatted to provide information clearly and unambiguously to the treating doctors, and should be organised with their use of the report in mind. In this sense, the report differs from the structured checklist, which is organised with the pathologists' workflow as a priority.

Uniformity in the format as well as in the data items of cancer reports between laboratories makes it easier for treating doctors to understand the reports; it is therefore seen as an important element of the systematic reporting of cancer. For guidance on formatting pathology reports, please refer to Appendix 2. An example of a pathology report is shown in Appendix 3.

Appendix 1 Pathology request form

This appendix describes the information that should be collected before the pathology test. Some of this information can be provided on generic pathology request forms; any additional information required specifically for the reporting of Malignant odontogenic tumours may be provided by the clinician on a separate request information sheet. An example request information sheet is included below. Elements which are in bold text are those which pathologists consider to be required information. Those in non-bold text are recommended.

Also included in this appendix are the procedures that are recommended before handover of specimens to the laboratory.

Patient information

- **Adequate demographic and request information should be provided with the specimen.**
 - Items relevant to cancer reporting protocols include:
 - patient name
 - date of birth
 - sex
 - identification and contact details of requesting doctor
 - date of request
 - Document whether or not the patient identifies as Aboriginal and/or Torres Strait Islander in Australia or Māori in New Zealand. This is in support of government initiatives to monitor the health of those who identify as indigenous, particularly in relation to cancer.
- The patient's health identifiers should be provided.
 - The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).
- The Australian Healthcare identifiers i.e., Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be use, where possible, to identify the requesting doctor.

Clinical Information

- **The anatomical site of the biopsy or resection must be recorded.**
 - Site is an important identifier especially when multiple biopsies are performed. For carcinomas that may involve more than one site it is recommended that the clinician identify all sites involved and that if possible the principal site of involvement be recorded.

Sufficient information is required to localise the lesion for subsequent therapy. A diagram or photograph can facilitate this.

Prognostic significance – the association between anatomical site and survival may be explained by the tumours site’s influence on metastasis to cervical lymph nodes.¹⁵⁻¹⁶
- **The laterality of the lesion must be recorded.**
 - Laterality information is needed for identification purposes
- **Clinical history must be recorded.**
- **The clinical diagnosis or differential diagnosis must be recorded.**
 - Providing the provisional clinical diagnosis or differential diagnosis improves clinico-pathological correlation and improves diagnostic accuracy.
- **The type of operation performed must be recorded.**
 - The type of operation performed will influence the subsequent handling of the specimen in the laboratory.
- **Preoperative radiological/imaging reports should ideally be available for review during pathological reporting of the surgical specimen, and key elements should be included with the clinical details (e.g., site and size).**

 ➤	Any neoadjuvant therapy administered should be recorded.
●	There is no agreed upon system for grading tumour regression in oral squamous cell carcinoma that has been treated with neoadjuvant therapy. However, a history of previous radiotherapy and/or chemotherapy should be included as histologic changes related to the therapy such as necrosis may affect interpretation of the tumour.

- **Record if this is a new primary cancer or a recurrence of a previous cancer, if known**
 - The term recurrence defines the return, reappearance or metastasis of cancer (of the same histology) after a disease-free period.

Recurrence should be classified as distant metastases or

regional (local) recurrence.

Regional (local) recurrence refers to the recurrence of cancer cells at the same site as the original (primary) tumour or the regional lymph nodes.

Distant metastasis refers to the spread of cancer of the same histologic type as the original (primary) tumour to distant organs or distant lymph nodes.

This information will provide an opportunity for previous reports to be reviewed during the reporting process, which may provide valuable information to the pathologist. This information also has implications for recording cancer incidence and evidence-based research.

- Comments should be included, if appropriate.
 - Space for free text should be included to encourage reporting of ambiguity, or for the addition of other comments.

Example Request Information Sheet

Malignant Odontogenic Tumours Histopathology Request Information



Family name

Given name(s)

Date of birth Date of request

Patient identifiers e.g. MRN, IHI or NHI (please indicate which)

Requesting doctor - name and contact details

Copy to doctor name and contact details

Ethnicity

Unknown/inadequately described

Aboriginal/Torres Strait Islander (AU)

Māori (NZ)

Other ethnicity:

CLINICAL INFORMATION

OR

ANATOMICAL SITE

LATERALITY

Not stated Left Right

CLINICAL HISTORY

OR

Not stated

CLINICAL OR DIFFERENTIAL DIAGNOSIS

OR

Not stated

TYPE OF OPERATION (select all that apply)

Not specified

OR

Debulking/curettage

Biopsy (excisional, incisional), *specify*

Resection, *specify*

Neck (lymph node) dissection*, *specify*

Other, *specify*

NEOADJUVANT THERAPY

Not administered

Administered, *specify type*

Chemotherapy

Radiotherapy

Targeted therapy, *specify if available*

Immunotherapy, *specify if available*

NEW PRIMARY CANCER OR RECURRENCE

New primary Recurrence - regional

Recurrence - distant

Details:

PRINCIPAL CLINICIAN

COMMENTS

* If a *neck dissection* is submitted, then a separate dataset is used to record the information.

V1.0 Request Info for MALIGNANT ODONTOGENIC TUMOURS Structured Reporting Protocol 1st Edition

The above [Request Information Sheet](#) is published to the RCPA website.

Appendix 2 Guidelines for formatting of a pathology report

Layout

Headings and spaces should be used to indicate subsections of the report, and heading hierarchies should be used where the LIS allows it. Heading hierarchies may be defined by a combination of case, font size, style and, if necessary, indentation.

Grouping similar data elements under headings and using 'white space' assists in rapid transfer of information.³⁷

Descriptive titles and headings should be consistent across the protocol, checklist and report.

When reporting on different tumour types, similar layout of headings and blocks of data should be used, and this layout should be maintained over time.

Consistent positioning speeds data transfer and, over time, may reduce the need for field descriptions or headings, thus reducing unnecessary information or 'clutter'.

Within any given subsection, information density should be optimised to assist in data assimilation and recall. The following strategies should be used:

Configure reports in such a way that data elements are 'chunked' into a single unit to help improve recall for the clinician.³⁷

Reduce 'clutter' to a minimum.³⁷ Thus, information that is not part of the protocol (e.g., billing information or SNOMED codes) should not appear on the reports or should be minimised.

Reduce the use of formatting elements (e.g., bold, underlining or use of footnotes) because these increase clutter and may distract the reader from the key information.

Where a structured report checklist is used as a template for the actual report, any values provided in the checklist but not applying to the case in question must be deleted from the formatted report.

Reports should be formatted with an understanding of the potential for the information to 'mutate' or be degraded as the report is transferred from the LIS to other health information systems.

As a report is transferred between systems:

- text characteristics such as font type, size, bold, italics and colour are often lost
- tables are likely to be corrupted as vertical alignment of text is lost when fixed font widths of the LIS are rendered as proportional fonts on screen or in print

- spaces, tabs and blank lines may be stripped from the report, disrupting the formatting
- supplementary reports may merge into the initial report.

Appendix 3 Example of a pathology report

For malignancies arising from lymph node specimens, refer to the [protocol for Head and Neck nodal excisions](#) where appropriate, in conjunction with this protocol.

Tshen, Georgina W. C/O Paradise Close Wreck Bay Resort Nar Nar Goon East, 3181 Female DOB 1/7/1951 MRN FMC1096785	Lab Ref: 19/P28460 Referred: 30/8/2019	Copy to: Dr G. Grey Rainforest Cancer Centre. 46 Smith Road, Woop Woop, 3478	Referred by: Dr V. Smith Suite 3, AJC Medical Centre, Bunyip Crescent Nar Nar Goon West, 3182
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ODONTOGENIC TUMOUR STRUCTURED REPORT Page 1 of 2

Diagnostic Summary

Type of specimen: right posterior body, angle and ramus of mandible
Tumour type: Ameloblastic carcinoma
Necrosis: Focal
Lymphovascular invasion: Not identified,
Perineural invasion: Not identified,
Margins: Closest margin is lingual cortical bony plane of resection 1mm

Type of specimen: Left neck levels IIA-III
Tumour dimensions: Not identified
Extranodal spread: Not identified
Status of salivary glands: Received, submandibular gland shows non-specific chronic sialadenitis with no evidence of involvement by tumour.

Supporting Information

CLINICAL

Operative procedure: Right hemimandibulectomy, supraomohyoid neck dissection (Level I-III)
Clinical comment: 66 yo male with ameloblastic carcinoma of right mandible. Right hemimandibulectomy plus right supraomohyoid neck dissection.

MACROSCOPIC

Specimen labelled: "submental triangle; right supraomohyoid dissection; jaw"
Specimen submitted: Surgical resection: neck dissection; right posterior body, angle and ramus of mandible
Tumour site: Right mandible: ramus, body; Right supraomohyoid neck levels IIA-III.
Maximum tumour dimension: 23 mm
Additional dimensions: 23 x 21 mm

Block identification key:

A1 – 1 node bisected; A2 – 2 nodes;
 B1-B2 – region Ib salivary gland; B3 – region IIa 1 node; B4 - region IIb fatty tissue; B5 – region III two nodes; B6 – region III three nodes; B7 – region III five nodes.
 C1 – shave of anterior most mucosal surface; C2-C4 – mucosal resection margin (lingual); C5-C7 – mucosal resection margin (buccal); C8-C9 – lingual soft tissue margin; C10-C13 – buccal soft tissue margin; C14 – anterior bony margin; C15 – posterior bony margin; C16 – “shave” of tumour full face.

MICROSCOPIC

Histological tumour type: Ameloblastic carcinoma
Histological grade: Not applicable
Necrosis: Present focally
Extent of invasion: Infiltration into soft tissue beyond the periosteum
 Involved overlying mucosa
Perineural invasion: Not identified
Lymphovascular invasion: Not identified

MARGIN STATUS: Not involved
Distance to Anterior & posterior bony margin: Cannot be assessed, not applicable
Distance to soft tissue margin: 1 mm
Distance from closest margin: 1 mm
Closest margin: lingual cortical bony plane of resection

Lymph node (LN) status

Lymph node laterality: Right
Nodes examined/Node levels/Nodes positive:
 Level IIA – 1 found; 0 involved
 Level IIB – 0 found; 0 involved
 Level III – 10 found; 0 involved
Soft tissue metastasis: Not identified
Extranodal extension (ENE): Not identified
Additional pathologic findings: Received submandibular gland shows non-specific chronic sialadenitis with no evidence of involvement by tumour.

Additional microscopic comments: The malignant change appears to have arisen in a pre-existing ameloblastoma.

ANCILLARY TESTS Not performed

Reported by Dr Bernard Beckstein

Authorised 4/9/2019

Appendix 4 WHO classification of tumours

WHO classification of odontogenic and maxillofacial bone tumours^{a32}

Descriptor	ICD-O codes
Odontogenic carcinomas	
Ameloblastic carcinoma	9270/3
Primary intraosseous carcinoma NOS	9270/3
Sclerosing odontogenic carcinoma	9270/3
Clear cell odontogenic carcinoma	9341/3
Ghost cell odontogenic carcinoma	9302/3
Odontogenic carcinosarcoma	8980/3
Odontogenic sarcomas	9330/3

^a The morphology codes are from the International Classification of Diseases for Oncology (ICD-O). Behaviour is coded /0 for benign tumours; /1 for unspecified, borderline, or uncertain behaviour; /2 for carcinoma in situ and grade III intraepithelial neoplasia; and /3 for malignant tumours.

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